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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/894,788    08/27/97    GIACOMONI    P    05725.0213

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HM22/0922

EXAMINER

CHANNAVATIAI, A. I.

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

09/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
**08/894,788**

Applicant(s)  
**Paolo Giacomoni**

Examiner  
**Lakshmi Channavajjala**

Group Art Unit  
**1615**



☒ Responsive to communication(s) filed on Jul 13, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 31-38, 40-54, and 56-66 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 31-38, 40-54, and 56-66 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

Receipt of amendment D, dated 7-13-00 is acknowledged.

#### *Response to Arguments*

1. Applicant's arguments filed on 7-13-00 have been fully considered but they are not persuasive.
2. Rejection of claims 31-38, 40-54 and 56-66 under 35 U.S.C. 103(a) as being unpatentable over US patent No. 5716625 (Hahn) in view of US patent No. 5358969 (Williamson) or Hahn in view of Wahl et al (Wahl) or Hahn in view of Williamson and Wahl.

Applicants argue that Hahn does not teach NO synthase inhibitors and Williamson does not teach NO synthase inhibitors as anti-irritants and hence the combination of references applied by the examiner lacks motivation. Applicants also argue that the teachings of Hahn are not generic for anti-irritants. The arguments are not persuasive because, Hahn teaches the theory of combining a substance that can cause irritation with an anti-irritant in the same composition. Although their teachings does not include a number of anti-irritants to make it generic, a skilled artisan would derive from the teachings of Hahn that including an irritant and anti-irritant in the same composition would prevent the irritation due to the irritant. Hahn teaches a number of cosmetically acceptable substances that cause irritation, which can vary from mild irritation to severe contact dermatitis. It is well known in the art that contact dermatitis is an inflammation of skin caused due to the contact with a substance and includes itching, scratching which is nothing but a result of skin irritation. Williamson teaches the claimed NO synthase

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inhibitors for treating a variety of inflammatory conditions including dermatitis. Therefore, it is the position of the examiner that the motivation to combine the teachings of Hahn and Williamson comes from the theory of Hahn and accordingly, it would have been obvious for one of an ordinary skill in the art to incorporate NO synthase inhibitor of Williamson in the pharmaceutical or cosmetic composition of Hahn containing skin irritants, with an expectation to inhibit any irritation and associated inflammation caused by the substances.

Applicants submit that the anti-inflammatory agents of Hahn are not interchangeable with anti-irritants of Williamson (or Wahl), as they act on different sensory stimuli. However, this argument is not pertinent because, in the instant case, the claims merely state cutaneous irritation and does not state as to which type of sensory stimulus is being acted upon by the claimed NO synthase inhibitors. Besides, Williamson teaches the claimed NO synthase inhibitors for the same skin irritation conditions as taught by Hahn. Further, applicants argument that Hahn states that the effect of any particular agent on nerve activity and sensation is difficult to predict and hence a skilled artisan would have no reasonable expectation to successfully use any anti-irritant in the teachings of Hahn is not persuasive because, from the teachings of Wahl or Williamson, a skilled artisan would have known that the activity of NO synthase inhibitors is very predictable (in treating skin conditions resulting from irritation). Hence the combination of the references is deemed to be proper.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is (703) 308-2438. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703-308-1235).



Lakshmi S. Channavajjala  
09/19/00

THURMAN K. PAGE  
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